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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,847	08/02/2007	John Robert Fritch	20750-050US1 83.US2.PCT	5896
26204 7590 08/20/2009 FISH & RICHARDSON P.C. P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER SHTERENGARTS, SAMANTHA L	
			ART UNIT 1626	PAPER NUMBER
			NOTIFICATION DATE 08/20/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/593,847	Applicant(s) FRITCH ET AL.	
	Examiner Samantha L. Shterengarts	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1, 26-27, 32, 35-40, 41, 45-46, 59, 67, 80, 91-92, 94-98, 101, 103-113, 115, 120, 122-127, 131, 155-156, 158-160 is/are pending in the application.

4a) Of the above claim(s) 120, 122-127, 131 (in part), and 159 is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>20 Feb 08</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims rejected are 1, 26-27, 32, 35-40, 41, 45-46, 59, 67, 80, 91-92, 94-98, 101, 103-113, 115, 131 (in part), 155-156, 158, and 160 .

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DETAILED ACTION

Priority

1. The instant application is a national stage entry of PCT/US04/23880, filed July 21, 2004, which claims priority to U.S. Provisional application no. 60/555,626, filed March 23, 2004.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on February 20, 2008 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. The IDS document was considered. A signed copy of form 1449 is enclosed herewith.

Election/Restrictions

3. Applicant's election with traverse of Group I in the reply filed on May 29, 2009 is acknowledged. Applicant's traversal is persuasive and Groups I, II, and IV are rejoined into Group 1, and Groups III and V are rejoined into Group 2.

4. Claims 1, 26-27, 32, 35-40, 41, 45-46, 59, 67, 80, 91-92, 94-98, 101, 103-113, 115, 131 (in part), 155-156, 158, and 160 are examined on their merits. Claims 120, 122-127, 131 (in part), and 159 are withdrawn for being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 26-27, 32, 35-40, 41, 45-46, 59, 67, 80, 91-92, 94-98, 101, 103-113, 115, and 160 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 32, 46, 59, 67, 80, 91, 101, and 108 recite the limitation "for a time and

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under conditions suitable for forming a compound of formula...” This is recited various times throughout these claims, and in regards to forming compounds of many formulae. The time and conditions *suitable* are indefinite and Examiner cannot ascertain what time and conditions are necessary for forming said compounds. The time period and conditions are not defined by the specification and the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 1, 26-27, 32, 35-40, 41, 45-46, 59, 67, 80, 91-92, 94-98, 101, 103-113, 115, 131 (in part), 155-156, 158, and 160 rejected under 35 U.S.C. 103(a) as being unpatentable over Behan et al. (U.S. Patent no. 6,140,509).

Determining the scope and contents of the prior art

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Behan et al. teaches a process for preparing compounds of obvious variants of instant formula I employing obvious variants of intermediates.

Ascertaining the differences between the prior art and the claims at issue

Behan et al. teaches a process for preparing a compound of formula I by reacting formula II with an isocyanate compound of formula III (Column 39 $IV + V \rightarrow I$). The process is carried out by Behan et al. in hydrocarbon solvents at various temperatures. It would be obvious for one of ordinary skill in the art to attempt a known process for preparing compounds of formula I at various temperatures and with various solvents to seek purer compounds with higher efficacy for the intended use. The motivation to use reduced temperature would be to inhibit impurity formation. Merely modifying the process conditions such as temperature and concentration is not a patentable modification, absent a showing of criticality. *In re Aller* 105 USPQ 233. Other independent processes of claim 91 (employing a base), 101 (employing a halogenating reagent), and 108 (employing an alkyl hydrazine) are also taught in the reaction schemes of Behan et al.

The difference between the instant claims and the prior art is that in the instant claims substituent R^4 cannot be hydrogen and in the prior art, there is a hydrogen substituent at this position.

Resolving the level of ordinary skill in the pertinent art – Prima facie case of obviousness

With regards to the H v. $-CH_3$ substitution, MPEP 2144.08.II.A.4(c) states, "...consider teachings of a preferred species within the genus. If such a species is structurally similar to that claimed, its disclosure may motivate one of ordinary skill in the art to choose the claimed species or subgenus from the genus, based on the reasonable expectation that structurally similar species usually have similar properties."

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To those skilled in the chemical art, one homologue is not an advance over an adjacent member of a homologous series. The reason for this is that one of ordinary skill, knowing the properties of one member of series, would know what properties to expect in adjacent members. Finally, hydrogen and methyl are deemed obvious variants. *In re Henze*, 85 USPQ 261 (1950), *In re Wood*, 199 USPQ 137 (CCPA 1978), and *In re Lohr*, 137 USPQ 548, 549 (CCPA 1963).

One of ordinary skill would be motivated, from the disclosure in the prior art, to make the modifications required to arrive at the instant invention with reasonable expectation of success for obtaining a compound with the same utility. The motivation to make the change would be to make additional compound for the quoted purpose.

Thus, the instant claims are *prima facie* obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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7. Claims 1, 26-27, 32, 35-40, 41, 45-46, 59, 67, 80, 91-92, 94-98, 101, 103-113, 115, 131 (in part), 155-156, 158, and 160 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-56 of copending application no. 11/883,043. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims fully encompass the copending claims of 11/883,043 in their processes.

Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samantha Shterengarts whose telephone number is (571)270-5316. The examiner can normally be reached on Monday thru Thursday 9-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samantha L. Shterengarts/
Examiner, Art Unit 1626

/Kamal A Saeed/
Primary Examiner, Art Unit 1626